In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-1512V UNPUBLISHED

TERRY PITTS,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 29, 2020

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Mollie Danielle Gorney, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On September 28, 2018, Terry Pitts filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the "Vaccine Act"). Petitioner alleges that he suffered injuries, including a shoulder injury related to vaccine administration ("SIRVA"), as a result of an influenza ("flu") vaccination administered to his left shoulder on October 8, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons stated below, I conclude that Petitioner has not established by preponderant evidence that the onset of his shoulder pain was within 48 hours of his October 8, 2016 vaccination.

I. Relevant Procedural History

Mr. Pitts filed his petition for compensation on September 28, 2018. ECF No. 1. Petitioner filed relevant medical records and a Statement of Completion by February 2019. ECF Nos. 7, 11-12. After reviewing the medical records that had been filed, on August 5, 2019, Respondent identified additional records that needed to be filed by Petitioner because they were either cut off or illegible. ECF No. 17. Respondent also indicated that he was opposed to settlement discussions at that time, and requested 60 days to file his report pursuant to Vaccine Rule 4(c). *Id.* In response, Petitioner filed a status report on September 20, 2019, representing that the best copies of the medical records that could be obtained had been previously provided, and that no additional records existed. ECF No. 19.

On October 4, 2019, Respondent filed his Rule 4(c) Report recommending that entitlement to compensation be denied under the terms of the Vaccine Act. Respondent's Report at 1. ECF No. 20. Respondent argued that "Petitioner first sought treatment for his alleged left shoulder injury on February 21, 2017, approximately five months after receiving the vaccine." *Id.* at 6. In the intervening time period, however, Petitioner saw his primary care physician "twice . . ., both appointments were approximately a month after the vaccination, and he never mentioned any left shoulder problems." *Id.* Respondent further argued Petitioner "made no mention of how long his left shoulder pain had been occurring or that he believed his pain to be related to the vaccination. *Id.* Additionally, Respondent argues that at a subsequent orthopedics appointment, Petitioner complained of pain "for four months," indicating that "his pain began after the flu shot." *Id.* Finally, Respondent argues that at Petitioner's physical therapy evaluation, "petitioner indicated that he noticed soreness in his left arm 'about 1 week later' after receiving the flu shot." *Id.*

In a Scheduling Order filed on October 8, 2019, I expressed my view that based on review of the existing record, an onset hearing was not necessary. ECF No. 21. I also noted that because this anticipated ruling related to a discrete factual issue, party briefs were not necessary, although both sides would be permitted the opportunity to submit additional evidence bearing on onset. *Id.* On December 12, 2019, without filing any additional evidence, Petitioner filed a Statement of Completion indicating that the record in this matter is now complete. ECF No. 22.

The matter is now ripe for adjudication.

II. Issue

At issue is whether the onset of Petitioner's left shoulder pain began within 48-hours after vaccination as set forth in the Vaccine Injury Table (and more specifically the

Table's "Qualifications and Aids to Interpretation" ("QAI"). 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination) and § 100.3(c)(10).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition as set forth in Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human*

Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3) and Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the following findings after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4 report, and any additional evidence filed:

- Mr. Pitts was administered a flu vaccine in his left deltoid on October 8, 2016. Petitioner (Pet.) Exhibit (Ex.) 1 at 1.
- At the time of the vaccination, Mr. Pitts had recently moved and was not working. Pet. Ex. 3 at 18. Mr. Pitts asserts that he had a noncontributory past medical history when he received the flu vaccine. Petition at 1.
- In his affidavit, Mr. Pitts averred that the pain he felt in his arm after the vaccination was immediate and intense, and did not resolve even after he left the doctor's office. Pet. Ex. 7 at 1. Mr. Pitts contends that he called his physician's (Dr. Oh's) office a few hours after his appointment mentioning that his arm still hurt, and as a result he was given a follow-up appointment on November 7, 2016. *Id.* Mr. Pitts states that the morning after the flu vaccine, he mentioned how severe his pain was to his wife. He states that he followed her suggestion to massage the area of the vaccine, but the pain did not go away. *Id.*
- On November 5, 2016, Mr. Pitts presented to Dr. Oh. Pet. Ex. 3 at 15. The "Reason for Appointment" states "1 month [follow up]." *Id.* The note states that hyperlipidemia, attention deficit hyperactivity disorder (ADHD), hypertension, and

- type 2 diabetes mellitus assessments were performed, and reviews of multiple body systems were unremarkable. Pet. Ex. 3 at 15-16. Specifically, musculoskeletal system states, "Joint pain denies." *Id.* at 16.
- Two days later, on November 7, 2016 approximately one month after Mr. Pitts's flu vaccination, and at the visit purportedly to address his alleged post-vaccination pain Mr. Pitts visited Dr. Oh again. Pet. Ex. 3 at 13. The assessments were the same as the November 5 appointment, although "encounter for immunization" was also documented. *Id.* Again, at this appointment, the review of the musculoskeletal system states, "Joint pain denies." *Id.*
- Mr. Pitts's affidavit does not mention the November 5, 2016 visit in his affidavit, but asserts in reference to the November 7, 2016 appointment that "a conversation and examination of my arm took place. I couldn't even raise my arm up to take off my shirt." Pet. Ex. 7 at 1. Mr. Pitts further asserts that he rated his pain as 8 out 10. Mr. Pitts states that at this appointment, he was referred to see a specialist (Dr. Levin) and he made the first available appointment which was in February of 2017. Id. Neither of these November 2016 assessments documents Mr. Pitts's account of this visit.
- On February 21, 2017, approximately four months and thirteen days after vaccination, Mr. Pitts presented to Dr. Oh again. Pet. Ex. 3 at 10. The "History of Present Illness" states, "[patient complains of] some pains in the left arm left shoulder pains he does total gym but is finding it difficult to do much exercise." Id. Mr. Pitts's diagnosis, among other things was "left shoulder pain." Id. at 11. Of note, at this visit, a review of the musculoskeletal system also stated, "Joint pain denies." Id. at 10.
- The next day on February 22, 2017, Mr. Pitts presented to an orthopedist, Dr. Steven Levin (the visit scheduled the preceding November). Pet. Ex. 4 at 8. Dr. Levin documented that Mr. Pitts complained of "left shoulder pain for 4 months after he got a flu shot in October. He said it specifically started after he got a flu shot. No prior problems with the shoulder whatsoever. He denies severe pain, fever, malaise, chills or sickness, just discomfort in and around the biceps area and into the shoulder, pain with overhead activity, pain at night. No fever, malaise, chills or sickness. No trauma. No treatment . . . [illegible] this point in time. He is concerned, however, and comes in for consultation. He said he had some instances of some mild numbness and tingling, but that since dissipated, no weakness in the arm." Id. Dr. Levin's impression was "Bursitis. I did tell him that I have seen in the past where patients get flu shots and it is reddened about where the injections done possibly in the bursa and they get an inflammatory bursitis and that is my diagnosis at this juncture in time. Therefore, I would like to at least start out treating conservatively with physical therapy, iontophoresis and then reassess in a month. If there is no improvement at that time, we will certainly consider further workup. I explained everything to him clearly, he understood, was in agreement." Id. at 9.

- Mr. Pitts presented to physical therapy (PT) on March 14, 2017, for an initial evaluation, on referral by Dr. Levin. Pet. Ex. 4 at 71. Mr. Pitts's chief complaint was left shoulder pain. *Id.* The initial evaluation notes that Mr. Pitts "[r]eceived flu shot in fall 2016 *about 1 week later* noticed soreness in [left] lateral arm. Attempted massage and stretching, but did not help pain. Progressively has been worsening and increased area of pain." *Id.* (emphasis added).
- Mr. Pitts followed up with Dr. Levin on April 3, 2017. Pet. Ex. 4 at 72. Dr. Levin noted that Mr. Pitts continued to have discomfort in his shoulder and limitation of motion despite going to therapy. Dr. Levin noted that, subjectively, Mr. Pitts had numbness and tingling going down his arm. Id. at 25. Dr. Levin also assessed, "[t]his all started after a flu injection. He may have developed some adhesive capsulitis due to protecting his shoulder form the pain of a flu shot and/or he might have developed some radiculopathy, it is difficult to discern. Given this scenario, I think it would be prudent to obtain an EMG as well as an MRI of his neck and shoulder." Id. at 25-26.
- Mr. Pitts followed up with Dr. Levin on April 17, 2017, to review the results of an EMG study and an MRI. Pet. Ex. 4 at 33. Dr. Levin indicated that Petitioner was a candidate for cortisone injection as well as aggressive therapy for adhesive capsulitis. Dr. Levin recommended a cortisone injection "because his symptoms started when he had his initial injection for the [sic] fluid, he is reticent to get an injection and therefore I said at least he should do the therapy protocol and likely he will improve with time." Id. at 33-34.
- By letter dated January 24, 2019, addressed "To Whom This May Concern:", Dr. Oh writes, "This letter is to state that I am Mr. Terry [sic] Pitt's primary care physician. During an appointment in early November 2016, Mr. Pitts mentioned to me that he was having shoulder pain that began immediately after he received his flu vaccine on 10/08/2016. This was the same left shoulder that he had received the [sic] flushot in. Thank you." Pet. Ex. 9 at 1.
- Mr. Pitts filed an affidavit from his wife who averred that Mr. Pitts "experienced extreme pain that began the same day that he received his flu shot." Pet. Ex. 6. at 1. Mr. Pitts's wife explained that "[t]he morning after the shot was given, [Mr. Pitts] and I discussed the pain he was in. When [Mr. Pitts] told me how much his harm hurt, I suggested that he rub the area." *Id*.

This case presents several issues regarding Petitioner's success in establishing onset consistent with the Table's 48-hour requirement. First, there is a four and one-half month records gap from vaccination to first efforts to treat Petitioner's alleged shoulder pain, which undermines somewhat Petitioner's onset contentions. It is reasonable to expect that the average Program claimant might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain.

This gap is compounded by the fact that Petitioner had *two* intervening medical visits between the flu vaccination and his first documented complaint – both of which

occurred within a month of the vaccine's administration. In addition, although Petitioner's sworn testimony maintains that he did call Dr. Oh's office the same day as his vaccination complaining of shoulder pain, the records from these two visits say little to nothing about the reason for the visit, with the November 7th record only making a generalized reference to "immunization," but without specificity for onset.

Petitioner has attempted to remedy these omissions by obtaining a statement from Dr. Oh clarifying what was spoken about. Although such after-the-fact statements can be deemed persuasive (especially to the extent they do not contradict prior record statements), they inherently are somewhat less probative than contemporaneous evidence. Sanchez v. Sec'y of Health & Human Servs., No. 11-685 V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), vacated on other grounds, Sanchez by & through Sanchez v. Sec'y of Health & Human Servs., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020) (presumption that contemporaneous records are usually more probative than after-the-fact witness statements "is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions"). The fact that the revising/amending statement about what was discussed was added and obtained after the litigation had commenced is also unhelpful (although it does not necessarily mean the subsequent statement is false).

The first set of records where Petitioner's shoulder pain (and the timeframe for its onset and progression) are more specifically discussed – from the February 2017 first visit to Dr. Levin, for example – only indicate vaguely that Mr. Pitts's pain began "after" vaccination. Then, the March 2017 PT visit contains the first direct reference to onset in any record, but places it as beginning a week *after* vaccination – not one or two days, and not immediately. Although *subsequent* records began to fix onset as closer-in-time to vaccination, if not immediately thereafter, the March record gains force from the fact that *none* of the immediately-prior records – even those close in time to vaccination, and at visits purportedly intended to address pain – contradicted it.

I acknowledge that the standard applied to SIRVA claims on the onset issue is fairly liberal, and will often permit a determination that onset began within the 48-hour timeframe set by the Table, based on records prepared a few months after vaccination, and/or corroborated by sworn witness statements intended to amplify otherwise-vague records. There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); Lowrie v. Sec'y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam,

968 F.2d 1226 (Fed. Cir. 1992)). But not every SIRVA claim can be so preponderantly established, and certainly not where the sequential and contemporaneous record does not lend support to the Petitioner's allegations. Petitioner *has* preponderantly established at least a causation-in-fact SIRVA injury claim sufficient to go forward on (since the record *does* at least support the conclusion that within a week of vaccination he felt shoulder pain). But the November 2016 and February-March 2017 records do not preponderantly support a 48-hour onset.

Accordingly, I find Petitioner has not preponderantly established that onset of his pain occurred within 48 hours of vaccination – meaning that he cannot proceed in this action with his Table SIRVA claim.

V. Scheduling Order

Accordingly, Petitioner's Table SIRVA claim is dismissed. Respondent shall file, by no later than <u>June 26, 2020</u>, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding, and specifically stating what, if any, objections he would lodge with respect to a non-Table, causation-infact version of the present claim.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master